REMARKS

Claims 1-21, 23, 28-34, 43, and 48-49 are currently pending. No claims are amended herein. The attached table summarizes information present in the Examples of the specification and does not contain any new matter. Each of the rejections is addressed below.

Finality of the Rejection is Premature

Applicants submit that the Office Action of March 18, 2009 set forth new grounds of rejection that had not been previously made in a prior non-final Office Action.

In the Office Action of May 15, 2009, Claim 23 was rejected under 35 U.S.C. § 103(a) as obvious over Kortschack in view of U.S. Patent No. 6,379,663 to Gill et al. (hereinafter "Gill"). In the current Office Action, the Examiner rejected Claim 23 under 35 U.S.C. § 103(a) as obvious over Kortschack in view of Michiels. The Examiner stated that the Applicants' amendment necessitated this new ground of rejection and accordingly, the Office Action was made final. However, Applicants submit that Claim 23 was not amended subsequent to the Office Action dated May 15, 2009.

Subsequent office actions shall not be made final where the Examiner introduces a new ground of rejection that is not necessitated by Applicant's amendment. MPEP § 706.07(a). If, on request by Applicant for reconsideration, the Primary Examiner finds the final rejection to have been premature, he or she should withdraw the finality of the rejection. MPEP § 706.07(d).

Applicants respectfully submit that a final rejection is improper here because the Examiner raised new grounds for rejecting Claim 23 and Applicants did not amend Claim 23. Therefore, Applicants respectfully request that the finality of the pending Office Action be withdrawn.

Rejections under 35 U.S.C. § 103(a)

It is well settled that the Examiner "bears the initial burden of presenting a *prima facie* case of unpatentability..." *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, the Applicant need not present arguments or evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish at least three elements. First, the prior art reference (or references when combined)

must teach or suggest all of the claim limitations: "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); ("the need to demonstrate the presence of all claim limitations in the prior art was not obviated [by KSR]", *Abbott Labs. v. Sandoz, Inc.*, 2007 WL 1549498, *4 (N.D. Ill. May 24, 2007)); *see also* M.P.E.P. § 2143.03. Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986); *Pharmastem Therapeutics v. Viacell, Inc.*, 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007); *see also M.P.E.P. § 2143.02*. And finally, the Examiner must articulate some reason to modify or combine the cited references that renders the claim obvious. Merely establishing that the claimed elements can be found in the prior art is not sufficient to establish a *prima facie* case of obviousness.

Claims 1-21, 23, 28-34, 43, and 48-49 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,117,460 to Kortschack (hereinafter "Kortschack") in view of GB 2367997 to Michiels et al. (hereinafter "Michiels"). Applicants respectfully traverse the present rejection.

The Examiner found Kortschack to disclose subjecting a meat product containing *Lactobacilli* to a pressure between 400 and 600 MPa at 20°C for 10 minutes to reduce the presence of the bacteria. The Examiner found that Kortschack fails to teach a treatment of about 5 minutes or less as presently claimed.

The Examiner found Michiels to disclose a pressure treatment time of between 1 second and 5 hours. The Examiner further found that it would have been obvious to treat the food of Kortschack for 5 minutes, 1 minute, or 1 second in order to pasteurize the food product.

Claim 1 and its dependents

Applicants submit that the combination of Kortschack and Michiels fails to make a prima facie case because the combination fails to disclose the features of Claim 1, there is no reason to make the combination, and the claimed features produced unexpected results.

The inventors have found that the methods disclosed in the application can kill spoilage organisms and increase the product's storage stability and thus shelf life while at the same time avoid heat treatment that will kill a culture that needs to remain viable in the product. Heat treatment will denature proteins and indiscriminately kill all organisms in the product, whether

they are spoilage microorganisms or desirable microorganisms. The inventors have found that pressure treating a food allows effective control of spoilage microorganisms while surprisingly having little or no impact on the viability of desirable microorganisms.

First, Claim 1 requires "selecting a food comprising at least one strain of a culture, said strain capable of surviving a pressure treatment at a predetermined pressure and pH" and a pressure treatment "wherein the treatment pressure reduces, delays, prevents or eliminates growth of spoilage microflora". Thus, the pressure treatment kills spoilage microflora but retains the desired strain that is capable of surviving the treatment conditions. Kortschack uses bacteria for flavor control and pH control but the pressure treatment is designed to ultimately kill **all** microorganisms present, not maintain some and kill others. (See column 4, line 53 to column 6, line 18; see also "The method in accordance with the present invention allows the manufacturer to inhibit the activities of the desirable as well as the undesirable microorganisms at a clearly defined timing by means of the high-pressure treatment." and "In any case the pH will remain stable in the semifinished products subsequent to the high-pressure treatment. There will be no further relevant biochemical processes." Col. 4, ll. 56-60 and 63-65).

Michiels is also concerned with inactivating substantially all of the bacteria and microorganisms present in the treated mixture. Michiels discloses that a high pressure treatment alone was not sufficient for their treatment step. ("It can be concluded from this brief overview that cold pressure treatment cannot be applied to pasteurize or sterilize non-acid food or other products to meet the existing microbiological criteria for heat pasteurization or sterilization, in spite of the potential to inactivate some microorganisms." See page 3). Michiels also discloses that their invention requires superatmospheric pressure **and** lactoperoxidase, plus heat treatment even with a treatment time of 15 minutes. See Examples 1-8.

Kortschack and Michiels do not want to have any microorganisms survive their treatment. Thus, they do not and would not select a product including a microorganism that would survive the pressure treatment conditions. They necessarily fail to disclose pre-selection of a product containing a desirable microorganism that will survive pressure treatment in sufficient quantities to be at a useful concentration in the final product. Because Kortschack and Michiels are focused on inactivating or killing all of the microorganisms they both fail to teach "selecting a food comprising at least one strain of a culture, said strain capable of surviving a pressure treatment at

a predetermined pressure and pH" and a pressure treatment "wherein the treatment pressure reduces, delays, prevents or eliminates growth of spoilage microflora". Accordingly, Applicants request withdrawal of the rejection of Claim 1 for at least this reason.

Second, there is no reason to use a pressure treatment of 5 minutes or less in the combination of Kortschack and Michiels. Kortschack discloses a pressure treatment of 10 minutes that decreased the concentration of *lactobacilli* in smoked sausages. Col. 6, lines 1-5. Applicants note that Michiels broadly discloses a pressure treatment duration of 1 second to 5 hours. However, the specific examples of Michiels use pressure treatments of 15 minutes.

The Examiner found that using a pressure treatment of 5 minutes or less was mere optimization in view of the cited art. Applicants respectfully disagree. There is no specific guidance to a person of skill in the art at the time of the invention to use or select a pressure treatment of about five minutes or less in Michiels or Kortschack. Optimization of the processes of Kortschack and Michiels, whose goals are to inactivate **all** of the bacteria and microorganisms, would not lead a person of skill in the art to use a pressure treatment of 5 minutes or less or to achieve a process including selective inactivation of bacteria. Michiels discloses that pressure alone is not sufficient so a person of skill in the art would not optimize to shorten the treatment time of Kortschack, which only discloses a treatment time of 10 minutes and nothing else. Further, Michiels teaches away from using a high pressure treatment without an additional treatment such as heat, peroxidase, etc. In view of Kortschack and Michiels, a person of skill in the art would not decrease the time of the pressure treatment to about 5 minutes or less because a person of skill in the art would not expect such a short duration to inactivate the bacteria.

Further, there are different process concerns for the processes of Kortschack and Michiels versus the claimed process. They are concerned with killing all microorganisms and would do everything to make sure that happens. There is nothing to suggest that a short pressure treatment in Kortschack would work well (which specifically does not include a heat treatment process). Moreover, neither of the references disclose trying to kill some microorganisms but preserve others or any reason to think that a pressure treatment would do so. For example, long treatment times can be undesirable in the processes disclosed in the present application because they can lead to a high level inactivation of the selected strain. See Example 28 of the present application.

Third, the effectiveness of the pressure treatment of the recited duration and selective killing of bacteria is unexpected. See the attached table summarizing the data in the Examples showing inactivation of spoilage organisms and acceptable amounts of the selected/desired organism remaining after the pressure treatment.

The inventors have found that pressure treating a food allows effective control of spoilage microorganisms while surprisingly having little or no impact on the viability of desirable microorganisms, such as those of Claim 9. Additional desirable organisms, such as starter cultures for use in yoghurt manufacture, are listed in Table 4 on page 26. As can be seen from the attached table, Applicants have demonstrated that a treatment pressure of at least 300 MPa for about 5 minutes or less of a food comprising at least one strain of a culture capable of surviving a pressure treatment at a predetermined pressure and pH is effective to retain that strain in a viable form while also reducing, delaying, preventing or eliminating growth of spoilage microflora.

As can be seen from column 9, spoilage organisms were reduced from a spoilage level to a non-detectable level that would promote suitable shelf stability. In view of the presence of both desirable and undesirable organisms, the treatment pressure and time conditions, and the result of maintaining a viable desirable culture while substantially eliminating undesirable microorganisms, Applicants submit that the data in the specification demonstrates unexpected results over the teachings of Kortschack and Michiels.

Furthermore, Applicants submit that it is not necessary for the claims to define a degree or quantification of reduction in bacterial growth because that will vary from application to application and species to species of spoilage microorganism.

For the reasons discussed above, Applicants respectfully request withdrawal of the rejection of Claim 1 and its dependents.

Claim 23

Clam 23 stands rejected by the combination of Kortschack and Michiels. Claim 23 recites "selecting a food comprising a bacterial strain selected from the group consisting of *Lactobacillus acidophilus* HN017 AGAL deposit number NM97/09515 dated 18 August 1997 and *Bifidobacterium lactis* HN019 AGAL deposit number NM97/09513 dated 18 August 1997".

The Examiner previously found that "Kortschack fails to disclose the use of probiotic strains claimed by applicant". Office Action dated May 15, 2009 at paragraph 33. Michiels fails to make up for this deficiency because it does not disclose *Lactobacillus acidophilus* or *Bifidobacterium lactis*, as claimed in Claim 23.

The use of the specific bacteria strains recited in Claim 23 is also more than an obvious variation of the combination of Kortschack and Michiels proposed by the Examiner. There is no reason to use these specific strains in the combination of Kortschack and Michiels because the treatments steps of Kortschack and Michiels are designed to kill the bacteria in the treated food product. There is also no reason to select strains that can survive some pressure treatment, instead Kortschack and Michiels want to select strains that will be killed.

As discussed above, the methods of Kortschack disclose deactivating the bacteria during the high pressure treatment after the meat product has reached a desired pH. Also, as discussed above, Michiels focuses on deactivating all of the bacteria during the pressure treatment step. Thus, the skilled artisan would want to select bacteria that would be killed and would expect the pressure treatment conditions disclosed in Kortschack and Michiels to deactivate the bacteria strains recited in Claim 23.

The skilled artisan would not expect any benefit from using the probiotic bacteria strains in the combination of Kortschack and Michiels and would not make the asserted combination. Accordingly, Applicants respectfully request withdrawal of this rejection for at least this reason.

Further, modifying Kortschack and Michiels to use any of the bacteria strains recited in Claim 23 would modify the principle of operation of Kortschack and Michiels because, as noted above, Kortschack and Michiels are explicitly concerned with deactivating all of the bacteria. Using a strain that survives would defeat the purpose of Kortschack and Michiels. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

For the reasons discussed above Applicants respectfully request withdrawal of the rejection of Claim 23.

Claims 11-16

For reasons similar to those discussed above with respect to Claim 23, there is no reason to use the *Bifidobacterium* and *Lactobacillus acidophilus* strains recited in Claims 11-13 and 15-16 with the combination of Kortschack and Michiels suggested by the Examiner. Accordingly, Applicants respectfully request withdrawal of the rejections of Claims 11-13 and 15-16 for this reason as well.

Claim 48

Claim 48 recites wherein the selected strain does not cause spoilage of the food. The lactobacillus of Kortschack causes undesirable changes in the meat products. Thus, the combination of Kortschack and Michiels also fails to disclose a process wherein the selected strain does not cause spoilage of the food. Accordingly, Applicants respectfully request withdrawal of the rejection of Claim 48 for this reason as well.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being madc to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Example	Desired organism	Spoilage organism	MPa	Temperature	Time (minutes)	pH	Desired organism after treatment	Spoilage organism after treatment	Comments
Reconstituted skim milk									
1	*Streptococcus thermophilus* 1%	Yeast 1.8×10^6 cfu/g	400	10°C	5	4.4	3.3×10^7 cfu/g	Not detectable	
2	*Lactobacillus helveticus* 1%	Mould 3.1×10^6 cfu/g	400	10°C	5	4.4	1.3×10^8 cfu/g	Not detectable	
3	*L. delbrueckii sub-species bulgaricus* 1%	Yeast 9.3×10^7 cfu/g	350	10°C	5	4.4	7.6×10^7 cfu/g	Not detectable	
4	*S. thermophilus* 1%	Yeast 3.5×10^6 cfu/g	400	10°C	5	4.4	6.8×10^2 cfu/g	Not detectable	
Yoghurt									
5	*S. thermophilus* and *L. delbrueckii sub-species bulgaricus* 1%	Mould and yeast 4.4×10^6 cfu/g	450	15°C	1	4.4	3.0×10^8 cfu/g and 1.4×10^8 cfu/g	Not detectable	
6	*S. thermophilus* and *L. delbrueckii sub-species bulgaricus* 1%	Mould and yeast 5.4×10^6 cfu/g	450	15°C	1	4.4	6.6×10^8 cfu/g	Not detectable	
7	*S. thermophilus* and *L. delbrueckii sub-species bulgaricus* 1%	Mould and yeast 7.9×10^6 cfu/mL	450	15°C	1	4.0	2.1×10^8 cfu/mL	Not detectable	
8	*S. thermophilus* and *L. delbrueckii sub-species bulgaricus* 1% each	Mould and yeast 3.0×10^6 cfu/g	450	15°C	1	4.0	1.8×10^8 cfu/g and 4.1×10^7 cfu/g	Not detectable	
9	*S. thermophilus* and *L. delbrueckii sub-species bulgaricus* 1% each	Mould and yeast 3.0×10^6 cfu/g	450	15°C	1	3.6	1.3×10^4 cfu/g	Not detectable	
10	*B. lactis* (1%) and *L.*	Nil	375	5°C	5	4.0	*B. lactis* of 1.3×10^7	Not	Untreated control had 1.2 x

	delbrueckii sub-species bulgaricus (0.25%)						cfu/g after four weeks storage	detectable	10^3 cfu/g yeasts and moulds after 4 weeks at 4°C.
11	*B. lactis* (1%) and *L. delbrueckii sub-species bulgaricus* (0.25%)	Nil	375	-	5	4.0	*B. lactis* 5.6 x 10^7 cfu/mL after four weeks storage	Not detectable	Untreated control had 3.2 x 10^2 cfu/mL yeasts and moulds.
Acid milk drink									
12	*Bifidobacterium* (5.7 x 10^7 cfu/mL)	Nil	350	15°C	5	4.0	4.7 x 10^7 cfu/mL	Nil	
13	*L. casei* (4.9 x 10^7 cfu/mL)	Nil	350	15°C	5	-	240 cfu/mL	Nil	
Orange juice									
14	*B. lactis* 10.6% (1.1 x 10^8 cfu/mL)	Yeast 2.2 x 10^7 cfu/mL	350	15°C	5	3.48	1.1 x 10^8 cfu/mL	Not detectable	
15	*B. lactis* 10.6%	Yeast 2.2 x 10^7 cfu/mL	300	15°C	5	3.48	1.1 x 10^8 cfu/mL	3.8 x 10^3 cfu/mL	Contaminated.
16	*B. lactis* 10.6%	Yeast 2.2 x 10^7 cfu/mL	600	15°C	5	3.48	4.1 x 10^6 cfu/mL	Not detectable	
Strain selection									
17	Various	Nil	350	–	5	–	Various	Nil	Identifies unsuitable and suitable strains.
Orange juice									
18	*Bifidobacterium* (>10^7)	Nil	600	–	5	4.0	>10^6 cfu/mL	Nil	
Sports drink									
19	*B. lactis* (9.2 x 10^7 cfu/mL)	Yeast 4.5 x 10^5 cfu/mL	400	–	5	-	2.7 x 10^7 cfu/mL	Not detectable	
Nutritional shake									
20	*B. lactis* (5.4 x 10^5	Yeast 5.4 x 10^5	500	–	5	~7.0	4.8 x 10^7 cfu/mL	Not	

	cfu/mL)	cfu/mL						detectable	
Yoghurt									
21	Rhodia culture MY900	Nil	400	–	5	4.1	7.9 x 10^7 cfu/g	Nil	
22	Rhodia culture MY900	Nil	450	15°C	5	–	3.0 x 10^7 cfu/mL	Nil	
23	Rhodia culture MY900	Nil	350 or 450	–	1	4.5	>10^7 cfu/g	Nil (450 MPa-treated)	Untreated control and 350 MPa-treated samples were contaminated after storage at 4°C for 95 days.
24	Rhodia culture MY900	Nil	430	–	1 second	4.5	>10^7 cfu/mL	Nil	Untreated control was contaminated after storage at 20°C for 15 days.
25	Rhodia culture MY900	Mould >10^5 cfu/g	360 to 500	–	1 second	4.5	>9 x 10^8 cfu/g	Nil at above 460 MPa	Yoghurt treated at 360 and 400 MPa contaminated. Yoghurt treated at 430 MPa had 2.4 log reduction.
Cultured beverage									
26	*B. lactis*		600	–	1 second	4.0	>10^8 cfu/g	Not detectable	Untreated control contaminated.
Yoghurt									
27	*S. thermophilus* and *L. bulgaricus*		350 or 450		5	3.9	<10^7 cfu/mL		
						4.1	>10^7 cfu/mL (350 MPa), <10^7 cfu/mL (450 MPa)		
28	*S. thermophilus* and *L. delbrueckii sub-species bulgaricus*	Yeast and mould	350		5		2.8 x 10^7 cfu/g	Log-cycle reduction 4.1	Time variation.

				10		5.7×10^5 cfu/g	Not detectable	
				15		1.9×10^5 cfu/g	Not detectable	
29	Various	Nil	400	5	4.4	Various	Nil	Most $>10^7$ cfu/mL (12 of 16); all $>10^7$ cfu/mL.